

REMARKS

I. Claimed Subject Matter

The invention is directed to a pharmaceutical or cosmetic composition comprising an oleaginous pharmaceutical or cosmetic carrier containing, by weight, 1-25 percent of a solidifying agent and 75-99 percent of a hydrophobic solvent and a therapeutically or cosmetically effective amount of a biologically active substance. The solidifying agent is selected from the group consisting of at least one long chain fatty alcohol having at least 15 carbon atoms in its carbon backbone and at least one fatty acid having at least 18 carbon atoms in its carbon backbone. The proportions and composition of the solidifying agent and hydrophobic solvent are selected such that under ambient conditions the carrier is semi-solid at rest and liquefies upon application of shear forces thereto, wherein the composition is free of particulate material that prevents liquification of the carrier upon application of shear force.

II. Claim Amendment

Claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-50 are pending in this application. With this response, claims 1, 4, 5, 7-12, 26, 29, 30, 32, and 34 are canceled; claim 37 is amended; and claims 52 and 53 are added.

Claim 37 recites that "the composition is free of particulate material that prevents liquification of the carrier upon application of shear force." Support for this statement is found throughout the specification. Specifically, the specification describes the carrier and compositions as semi-solid at rest and liquid upon application of shear force (page 1, lines 25-

28). The amendment now explicitly recites what is implicit in this statement, namely, that the composition does not contain insoluble particulate material that would prevent liquification upon shear stress.

III. Written Description Rejection

Claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-50 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement because the added term “solid-free” is not described in the specification and is considered new matter. The claims as amended no longer recite “solid-free;” and the rejection may be withdrawn.

The examiner objects to the term “solid-free” because it is not literally present in the specification. To the extent that the examiner has a similar objection to recitation of a composition that is free of particulate material that prevents liquification of the carrier upon application of shear force, applicants point out that this recitation merely describes a feature of the invention that is inherent in the rheological properties and compositional formulations described in the specification. The compositions of the invention do not mention particulate additives and require only an appropriate proportion and composition of solidifying agent and hydrophobic solvent such that under ambient conditions the carrier is semi-solid at rest and liquefies upon application of shear forces thereto. Notably, the solidifying agents of the present invention are not “particulate,” as they dissolve in the hydrophobic solvent. The specification does not explicitly state that the compositions are particulate-free; however, particulate additives would result in a paste or other non-liquid physical state upon application of shear forces, as would be apparent to one skilled in the art of topical formulations and rheological sciences.

IV. Indefiniteness Rejection

Claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the office action states that it is unclear how a solid-free carrier can at the same time be semi-solid.

The current claims do not refer to a solid-free carrier and the rejection is moot.

V. Rejection over U.S. Patent No. 6,224,888 to Vatter et al.

Claims 1, 4, 5, 7-12, 26, 29-30, 32-37, 40-41 and 43-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable to United States Patent No. 6,224,888 to Vatter et al. ("Vatter"). Applicants respectfully traverse the rejection. Applicants maintain their position that the Vatter patent does not suggest the instantly claimed cosmetic or pharmaceutical carrier because the Vatter compositions do not exhibit the instantly claimed carrier properties, namely, that the carrier is semi-solid at rest and liquefies upon application of shear force thereto because the Vatter compositions contain high levels of insoluble particulate matter that prevent shear liquification.

The compositions disclosed in Vatter would not liquefy upon application of shear force because of the presence of oil-insoluble powders in each disclosed composition (generally in concentrations exceeding 6%). The presence of such solids has been previously established in the communication submitted April 17, 2003. Such solids include inorganic salts, *e.g.*, titanium oxide and zirconium aluminum; silica; and pigments. The products described by Vatter require a solid consistency and should not be flowable, in order to remain on the application site. The

presence of such solids would prevent the product from being liquefied upon application of shear force.

One of skill in the art, reading Vatter, would understand that the high level of insoluble solids in the Vatter compositions prevents the liquification and flow of the composition upon application of a shear force. Thus, even if hydrophobic solvents and solidifying agents were included in the appropriate proportions in the Vatter compositions (which is not the case, see communications dated October 16, 2002 and April 17, 2003), the addition of solids teaches away from a composition that liquefies under application of shear force.

VI. Rejection over U. S. Patent 6,224,888 to Vatter further in view of U. S. Patent 4,992,478 to Geria

Applicants respectfully traverse the rejection of claim 51. A *prima facie* case of obviousness requires that (1) the prior art suggest to one of ordinary skill in the art that they should make the claimed composition. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

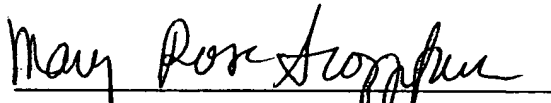
In this case, the cited prior art does not provide the suggestion or a reasonable expectation of success. Even if, the compositions of Vatter were modified with the medicaments of Geria, the result would not be the applicant's claimed invention. Rather, the result would be a composition that lacked the property of being semi-solid at rest and liquefying upon application of shear force. Furthermore, the disclosure of Geria does nothing to remedy the failure of Vatter and cannot therefore, either alone or in combination, render the claimed invention obvious.

VII. Conclusion

All currently pending claims are believed to be in conditions of allowance in light of the foregoing amendments and remarks, and an early notice thereof is respectfully solicited.

In addition, enclosed herewith please find a copy of the Petition for Three-Month extension of time with instructions to charge the required fee to Deposit Account No. 08-0219 which was filed in this application on June 11, 2003. Applicants submit that no further extension of time or fee is required. However, if further extensions or fees are required, this paper should be considered a constructive petition for any such extension and authorization to charge the required fee to Deposit Account No. 08-0219.

Respectfully submitted,


Mary Rose Scozzafava, Ph.D.
Registration No. 36,268

Dated: December 11, 2003

HALE AND DORR LLP
60 State Street
Boston, MA 02109
Phone: 617-526-6000
Fax: 617-526-500